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William J. McNichol, Jr., Esquire
Reed Smith, LLP
2500 One Liberty Place
1650 Market Street
Philadelphia, PA 19103-7301

EXAMINER

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RECORD OF ORAL HEARING
UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MANFRED BOHN, KARL THEODOR KRAEM,
and ASTRID MARKUS

Appeal 2009-000839
Application 10/606,229
Technology Center 1600

Oral Hearing Held: June 25, 2009

Before DEMETRA J. MILLS, LORA M. GREEN, and
MELANIE L. McCOLLUM, *Administrative Patent Judges*.

APPEARANCES:

ON BEHALF OF THE APPELLANTS:

William J. McNichol, Jr., Esquire
REED SMITH, LLP
2500 One Liberty Place
1650 Market Street
Philadelphia, Pennsylvania 19103-7301

PROCEEDINGS

2 MS. BEAN: Good morning. Calendar No. 66. Mr. McNichol.

3 JUDGE MILLS: Okay, thank you.

4 MS. BEAN: You're welcome.

5 JUDGE MILLS: Well, Mr. McNichol, I'd just like to let you know, at
6 least two of us are very familiar with the facts in this case, because we were
7 on the first decision that was filed.

8 MR. MCNICHOL: Good.

9 JUDGE MILLS: So we have a full docket this morning, and if you
10 would like to just focus your arguments as to what you think are most
11 particular for you, we'd appreciate it.

12 MR. MCNICHOL: I will, and you've also answered my first question
13 which is I have two appeals this morning back to back, and you're telling me
14 this is the Bohn appeal dealing with the treatment for seborrheic dermatitis?

15 JUDGE MILLS: Yeah, yeah. Okay.

16 JUDGE GREEN: Yeah, this is the seborrheic dermatitis, yes.

17 MR. MCNICHOL: Yeah, okay.

18 JUDGE MILLS: Oh, bone you said. Sorry.

19 MR. MCNICHOL: Yes.

20 JUDGE MILLS: I was wondering -- okay.

21 MR. MCNICHOL: Yes. No, not bones like in your --

22 JUDGE MILLS: Yeah, Bohn the inventor. I see.

23 MR. MCNICHOL: Okay. Thank you and good morning. This
24 application as you know does deal with a method of treating seborrheic
25 dermatitis with a Ciclopirox shampoo having a certain pH, and the invention

1 has been a breakthrough in the treatment of seborrheic dermatitis, and as I'll
2 get to when I discuss the commercial success, it has actually displaced the
3 previous treatments that were available. Two different commercial products
4 have done this, slightly different embodiments, all within the scope of the
5 claims, and they've done so at a premium price, so we'll get to that in a little
6 bit more detail.

7 Turning right, I think, to the prior art that's here, the Examiner has
8 cited the Dittmar '106 patent which discloses a Ciclopirox shampoo to treat
9 dandruff. The Examiner's initial position was that dandruff was the same as
10 seborrheic dermatitis, and the Examiner has stepped away from that. It was
11 an untenable position, and the Examiner now concedes that they are
12 different conditions, and he did so at page 4 of the Examiner's Answer.

13 To get from Dittmar using a shampoo to a Ciclopirox shampoo to treat
14 dandruff to the use of it to treat a different condition, seborrheic dermatitis,
15 the Examiner relies principally on Hanel. Actually, the Examiner relies
16 exclusively on the abstract of Hanel and makes a point of saying so probably
17 because the rest of Hanel is in German. I think the Examiner makes too
18 much of Hanel and mischaracterizes Hanel, and I'd like to speak directly to
19 what the Examiner does with Hanel.

20 Hanel reports the use of a Ciclopirox cream, okay, to treat
21 inflammatory fungal infections in AIDS patients, okay. That's the most
22 important thing to take away from Hanel, okay. He deals with a very
23 specific population with a very specific underlying disorder for the purpose
24 of treating fungal infections, inflammatory fungal infections. If you look at
25 Hanel's data, it's all based on the use of this antifungal to treat inflammatory

1 fungal infections in AIDS patients. AIDS patients, of course, are prone to
2 opportunistic infections, generally fungal infections in particular, and when
3 Hanel was treating these opportunistic fungal infections, he noticed that
4 when they had some eczema, seborrheic eczema, it got better, okay, because
5 the inflammation associated with it was reduced, okay. The Examiner goes
6 from that observation to a general conclusion that Ciclopirox treats
7 seborrheic dermatitis, okay.

8 JUDGE GREEN: Are you arguing that seborrheic eczema and
9 seborrheic dermatitis are not the same condition?

10 MR. MCNICHOL: We have argued that, but for the moment I'm
11 going to accept the Examiner's position that they are the same condition.

12 JUDGE GREEN: I mean because you haven't admitted it, but you
13 haven't provided any evidence that I can see on the record on appeal that
14 they are different.

15 MR. MCNICHOL: The Examiner has cited a Google reference. I
16 wouldn't want my doctor to treat me on the basis of a Google reference but I
17 mean we'll -- as I say, we'll --

18 JUDGE GREEN: Oh, I understand that, but we're --

19 MR. MCNICHOL: -- for purposes of the --

20 JUDGE GREEN: -- we're limited to the record in front of us --

21 MR. MCNICHOL: Sure.

22 JUDGE GREEN: -- so he provided some evidence. You haven't --

23 MR. MCNICHOL: And I'm arguing right now -- accepting that for
24 that proposition.

25 JUDGE GREEN: Okay.

1 MR. MCNICHOL: For purposes of immediate discussion.

2 AIDS patients, because they are special population, present special
3 conditions and the art, the record before us, Judge Green, is very clear that
4 seborrheic dermatitis in an AIDS patient is different than any other
5 seborrheic dermatitis.

6 JUDGE GREEN: Can you tell me where this is in your Appeal Brief
7 or your Reply Brief?

8 MR. MCNICHOL: Absolutely. If you were to go to the Wartzman
9 (phonetic sp.) declaration, attachment or appendix or Exhibit A, bridging
10 pages 4 and 5 where in dermatology and general medicine, development of
11 seborrheic dermatitis is a unique clue to the presence of HIV infection. The
12 expression of the disease differs in several respects from the classic form
13 seen in HIV-seronegative individuals, citing references. The distribution is
14 extensive, treatment difficult, even the histologic changes differ somewhat
15 from those seen in commonly encountered seborrheic dermatitis. The
16 increased incidence and severity of seborrheic dermatitis in HIV-positive
17 individuals led to speculation that unchecked growth of *Pityrosporum* in
18 immuno-suppressed patients is responsible. However, studies that compared
19 *Pityrosporum* culture in AIDS patients with and without seborrheic
20 dermatitis failed to demonstrate correlation.

21 JUDGE GREEN: Now does --

22 MR. MCNICHOL: The point here is that --

23 JUDGE GREEN: Does Wartzman discuss this in his declaration?

24 MR. MCNICHOL: He mentions it, this particular point. When the
25 Wartzman declaration was submitted, Hanel hadn't yet been of record, okay.

1 JUDGE GREEN: I understand that but I'm just, you know --

2 MR. MCNICHOL: So the short answer to your question is no,
3 because Hanel was not in the record when Wartzman submitted the
4 declaration.

5 JUDGE GREEN: And do you specifically address this in your appeal
6 brief?

7 MR. MCNICHOL: We do address the point that it -- Hanel is
8 different, yes.

9 JUDGE GREEN: No, I'm -- but as to the AIDS patients?

10 MR. MCNICHOL: I think it's in the face of Hanel. I don't -- I'm not
11 sure whether it appears in express terms in the brief.

12 JUDGE GREEN: And then I mean your claim 1 also encompasses
13 treatment of AIDS patients.

14 JUDGE MCCOLLUM: With --

15 JUDGE GREEN: Seborrheic eczema.

16 JUDGE MCCOLLUM: -- dermatitis.

17 MR. MCNICHOL: It would -- it doesn't differentiate, okay.

18 JUDGE GREEN: Right.

19 MR. MCNICHOL: But the claim deals with use of shampoos.

20 JUDGE GREEN: I understand that, but you're saying this is a
21 specific patient population. If -- even if an HIV patient was treated with
22 your shampoo, if we had that reference, that would be an anticipating
23 reference even though there are differences between -- there may be
24 differences between an AIDS patient and the general population.

25

1 MR. MCNICHOL: No, it would not be an anticipatory reference,
2 because Hanel used a cream.

3 JUDGE GREEN: No, no. I said if there were a reference out there
4 that used a shampoo to treat an AIDS patient, even though there may be
5 differences in seborrheic dermatitis in AIDS patients and the general
6 population, it would be an anticipating --

7 MR. MCNICHOL: Hypothetically.

8 JUDGE GREEN: Yes, I'm saying hypothetically if we had that
9 reference it would still be an anticipating --

10 MR. MCNICHOL: Right, but we don't.

11 JUDGE GREEN: -- reference as to claim 1.

12 MR. MCNICHOL: But we don't.

13 JUDGE GREEN: Right, I understand that.

14 MR. MCNICHOL: Okay. All right. My point about Hanel is simply
15 this. The Examiner tortures out of Hanel a conclusion that not even Hanel
16 would offer. If you look at Hanel's English language summary, the
17 conclusion he draws is that the antimycotic compound -- which is his
18 abbreviation for Ciclopirox, offers a possibility to treat inflammatory
19 mycoses without using corticosteroid combinations because he -- prior than
20 that, he discusses the fact that they -- that the way that AIDS patients with
21 seborrheic dermatitis are treated is with a combination of an antifungal and a
22 steroid.

23 Hanel doesn't make any generalizations beyond the use of creams in
24 AIDS patients, and that reflects the understanding in the art of what he was
25

1 dealing with there. I mean it's all over his key words, and it's all over his
2 abstract. It's the way you have to understand Hanel. But even if --

3 JUDGE GREEN: So you're arguing that one of ordinary skill in the
4 art would understand or read Hanel to say that you have to use a cream in
5 these type of treatments?

6 MR. MCNICHOL: No, I wouldn't say --

7 JUDGE GREEN: That it's not dependent on the compound but that
8 it's dependent on the vehicle?

9 MR. MCNICHOL: I didn't say that.

10 JUDGE GREEN: Well, I'm trying to figure out what you are trying
11 to say.

12 MR. MCNICHOL: Well, what I am saying is that there's -- to the
13 extent that Hanel offers a suggestion to modify Dittmar in some way or use
14 Dittmar differently, okay, the Examiner stretches it too far, okay. The
15 Examiner says that because Hanel in the Examiner's view describes the
16 ability of Ciclopirox to treat seborrheic dermatitis generally, okay, you can
17 then generalize Dittmar based on that suggestion, okay. That is how I
18 understand the way you would have to analyze an obviousness rejection
19 combining Hanel and Dittmar.

20 Our view is that it doesn't provide that suggestion, because it deals
21 with a unique set of people who have a unique set -- the disease apparently
22 has a different etiology if you're looking at that and a different course. But
23 even if you were to accept the position that that -- there is a suggestion,
24 okay, there, we believe that that suggestion, that prima facie case of
25 obviousness, is rebutted by showing of commercial success that the

1 Examiner first helped build and then ignored. The Kriel declaration
2 describes the commercial success of one of the two commercial products
3 that was -- that embodies the invention, and the Kriel declaration makes the
4 point that the product is promoted for this disease which, by the way, is a
5 very serious and potentially disfiguring disease, sold to doctors. It's not
6 advertised like Viagra or Rogaine or something like that. Insurance
7 companies don't reimburse for things that don't work. It sells at a premium
8 price and has still managed to displace the prior art treatments, okay.

9 Now that is my client's product, and it had the hard data that Mr. Kriel
10 could attest to in his declaration.

11 JUDGE GREEN: But we don't have the hard -- we don't have the
12 commercial sales data, correct?

13 MR. MCNICHOL: For -- you have what's attached to the Kriel
14 declaration, yeah.

15 JUDGE GREEN: Okay, then somehow it didn't get into our file, so I
16 will have to look for that.

17 MR. MCNICHOL: Okay. So the -- I mean the Kriel declaration is --
18 it contains data.

19 JUDGE GREEN: Okay, and then --

20 MR. MCNICHOL: But the Stieprox is the other commercial product
21 that the Examiner found and that we already knew about but is not ours, and
22 it also embodies the invention. They use different types of surfactants. The
23 specification in the claims talk about anionic, amphoteric and nonionic,
24 nonionic, anionic and amphoteric surfactants used in the shampoo.

25 JUDGE GREEN: Who is -- who owns the other product?

1 MR. MCNICHOL: Stieprox? Stiefel.

2 JUDGE GREEN: Stiefel?

3 MR. MCNICHOL: Yes, and they sell it in Canada.

4 JUDGE GREEN: Okay.

5 MR. MCNICHOL: They have not come into the United States we
6 believe because they know this patent application is sitting here, okay.

7 JUDGE GREEN: Okay.

8 MR. MCNICHOL: And they use -- of those three surfactants, they
9 use two that are different than the ones we use. There's overlap, but they
10 don't use the same ones, and it's flying off the shelves in Canada.

11 JUDGE GREEN: But you both use the same one active compound?

12 MR. MCNICHOL: Ciclopirox, yes.

13 JUDGE GREEN: Right, or your claim -- I mean I do -- your -- the
14 Examiner has pointed out that your genus encompasses a huge number of
15 compounds. I mean I admit that you don't have to show for every
16 compound but you have -- I think you do have to bring in some kind of
17 evidence that this nexus, that this one compound is representative of your
18 huge genus that you're claiming.

19 MR. MCNICHOL: Sure. If I can address the nexus issue which is
20 obviously very important. When the Examiner saw that -- found on her own
21 Stieprox, and she took that to be -- mistakenly took it to be the same product,
22 she said well, you know, your nexus only exists as to the specific surfactants
23 that you're using and suggested allowability if we were -- if we narrowed the
24 claim down to those specific surfactants. Stieprox was using anionic and
25 amphoteric, and we said time out. You have to -- you got a commercially

1 successful embodiment of the invention but the wrong embodiment. There's
2 two out there, and that fell apart. The Examiner now in the briefing won't
3 even acknowledge Stieprox, okay, which we think is a serious error that has
4 to be addressed.

5 It -- and so our briefing and our arguments and our head-butting to
6 date has been over that aspect of the breadth of the showing, and I have
7 taken that to mean that the Examiner's comments boilerplate about the
8 breadth of the showing to be in reference to the surfactants. If the Board is
9 saying that the active ingredient is a different aspect than you -- and that,
10 you know, the claim would be allowable if restricted to that particular active
11 ingredient, it's a different issue. I'm -- I suppose we could work with that,
12 but our thought process to date in our interactions with the Examiner in the
13 rejections below were based on the surfactants not the breadth of the active
14 ingredients, so I take your point.

15 JUDGE GREEN: Yeah, I would think that the more difficult issue is
16 the active -- the breadth of the active ingredient.

17 MR. MCNICHOL: I -- yes.

18 JUDGE MCCOLLUM: Can I just confirm the active ingredient that's
19 in the commercial embodiments, that is the same active ingredient that is --
20 that are in the Dittmar and Hanel? Is that correct?

21 MR. MCNICHOL: I believe that they describe more than one
22 compound within the class, but the compound that's in both of the
23 commercial products is also described in Dittmar, and Ciclopirox is in
24 Dittmar and Hanel.

25 JUDGE MCCOLLUM: Okay, just wanted to confirm that that --

1 MR. MCNICHOL: And those sat there for almost a decade, and
2 nobody commercialized them for this.

3 JUDGE MCCOLLUM: Okay.

4 MR. MCNICHOL: And when we did, okay, and when our competitor
5 did but just across the border in Canada, okay, it displaced all the prior art
6 products that had been used for decades or more in the treatment of this
7 disease at a premium price. So we feel that this is in many respects a unique
8 showing of commercial success, although perhaps you've heard somebody
9 come before you and say that before. But typically you don't have two
10 different commercial products at different points in the spectrum of the
11 claims showing that commercial success. My client doesn't have a presence
12 in Canada to sell its product so -- that I know of at least, and so the Stiefel
13 sort of operates out there, and they won't come into the United States for
14 whatever reason, we think because this application is lurking. And they've
15 formulated the surfactants differently.

16 If the claim -- the application obviously will support a claim to the
17 Ciclopirox alone. I'm not sure -- I look very quickly here -- I don't believe
18 that the -- there's a specific claim that calls out Ciclopirox. But clearly the
19 claim -- the application supports that, and if that's allowable subject matter,
20 it's something that we could deal with.

21 JUDGE MILLS: You don't have any argument that Dittmar does
22 disclose the surfactant that you're claiming also, correct? Your position is
23 that it doesn't -- the combination of references do not disclose a treatment of
24 seborrheic dermatitis?

25 MR. MCNICHOL: Correct.

1 JUDGE MILLS: Okay.

2 MR. MCNICHOL: Dittmar is a shampoo that obviously if it's a
3 shampoo it's going to have surfactants.

4 JUDGE MILLS: Surfactants, okay.

5 MR. MCNICHOL: But it treats -- one last point, unless you have
6 further questions on this one, is the blurring of the distinction between
7 dandruff and other disorders, and there's been this sort of mistaken view that
8 they were identical and then there was this -- now as I see in the appeal
9 briefs that well, they're similar in some way. I think that argument that
10 they're similar because there's flaking of the skin ignores the underlying
11 differences between the disorders. One is an inflammatory disorder,
12 seborrheic dermatitis. Dandruff is not an inflammatory disorder. They're
13 localized differently. Dandruff is found on a person's scalp, seborrheic
14 dermatitis typically elsewhere, although it can come on the scalp. Their
15 causation is different, and if you were going to say that anything associated
16 with flaking of the skin or peeling of the skin is the same as anything else
17 that's associated with that, then you have to lump in together sunburn. It
18 just proves way too much, and there is nothing in the art that suggests that
19 all skin diseases or even these two skin diseases are the same in their
20 etiology or how they would be treated just because they involve flaking of
21 the skin. It's a common symptom of a number of different disorders, but
22 symptoms aren't the same as an underlying disorder. You can have a
23 headache because you're hung over. You can have a headache because you
24 have underlying migraine conditions. You have have a headache because of
25 sinus pressure. Symptoms don't equal diseases, and you would treat a

1 headache if you have sinus congestion differently than if you are -- you're
2 suffering from migraine disorders. It's different sort of circumstance.
3 Although you might take an aspirin to get some symptomatic relief, you're
4 not treating the underlying disorder, and that's what we're talking about here
5 is treating underlying disorders.

6 JUDGE MILLS: Well, I believe you've helped us understand the --
7 your position with respect to the claims in the case.

8 MR. MCNICHOL: Okay, thank you.

9 JUDGE GREEN: I actually have one more question.

10 JUDGE MILLS: You have one more question?

11 MR. MCNICHOL: Certainly.

12 JUDGE GREEN: As to the embodiment that's shown in Canada, do
13 you have any data regarding the numbers as to that particular -- or because
14 you keep telling me that it's kind of displaced everything else in Canada.

15 MR. MCNICHOL: Yeah.

16 JUDGE GREEN: Is that in the application as well?

17 MR. MCNICHOL: The Examiner found evidence of that, but because
18 we didn't have access to our -- to the other company's hard data, it was
19 difficult for us to come forward, and that's why we didn't.

20 JUDGE GREEN: Okay.

21 MR. MCNICHOL: But the Examiner found information on her own
22 to that effect, and it was sufficient in her mind. Frankly, we thought that
23 without hard data, you know, the Examiner would simply ignore it. So we
24 went with the data that we had for our own product. We could say we had
25 this kind of sales and all that kind of stuff. The Examiner to our pleasant

1 surprise was -- found it on her own and found it sufficient, and we think it is
2 sufficient, but we were being cautious about the presentation of what we
3 took to be our best case. But there is no question that in Canada, Stieprox is
4 A, a different embodiment with respect to the surfactants used and is selling
5 gangbusters.

6 JUDGE GREEN: Yeah, but it's not your position that the surfactants
7 really change. It's mostly the properties of the active ingredients?

8 MR. MCNICHOL: It's the specific surfactants aren't necessarily
9 important, although you can optimize a product by, you know, that way.

10 JUDGE GREEN: I understand that.

11 MR. MCNICHOL: But it has to be done with a cleanser, okay, with a
12 surfactant, because that does have an effect on how the active ingredient is
13 delivered. It's not trivial, the fact that it's delivered in a shampoo. And you
14 have to have the active ingredient delivered that way, and it turns out that
15 that makes for a far superior product, and that's why it sells so darn well,
16 displacing everything else, and people will in fact pay a premium to get it.
17 So the specific surfactants aren't the point. The point is that you must have
18 surfactants so that you can deliver it in the shampoo.

19 JUDGE GREEN: Okay.

20 JUDGE MILLS: I do have one recommendation. If prosecution
21 should continue in the application, and you have any marketing materials for
22 the other product or any type of information that you might have that might
23 be beneficial to strengthen any patent that you might receive, to submit it in
24 evidence.

25 MR. MCNICHOL: You're referring to the Stieprox?

1 JUDGE MILLS: Stieprox, yes.

2 MR. MCNICHOL: Yeah. I guess the reason we didn't was that once
3 the Examiner kept -- I don't know of any other case where examiners come
4 forward to add to our commercial success argument. So I guess that's why
5 we didn't. We figured once you've gotten the Examiner saying that you're
6 commercially successful, you figure shut up and take that point.

7 JUDGE MILLS: Okay, very good. Okay, I don't think there are any
8 more questions? Melanie?

9 JUDGE MCCOLLUM: No.

10 JUDGE MILLS: No, okay, we're good. Thank you.

11 (Whereupon, the hearing concluded on June 25, 2009.)
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